JAN 2 8 2005

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K043014

1. Submitter's Identification:

Mr. Yang Ying
Shijiazhuang Tillotson Rubber Products Co., Ltd.
Donggao Industrial Zone
Zanhuang, Hebei Province
P.R. China

Date Summary Prepared: October 06, 2004

2. Name of the Device:

Shijiazhuang Tillotson Rubber Products Co., Ltd.

Powder Free Natural Rubber Latex Patient Examination Gloves with a Protein Labeling Claim (50 micrograms or less) and Made from Allotex® an Enzyme Treated Natural Rubber Latex

3. Predicate Device Information:

Syntex Healthcare Products Co., Ltd.

Powder Free Latex Examination Glove with Protein Labeling Claim (50 micrograms or less) (K021059)

4. Device Description:

Classified by FDA's General and Plastic Surgery Device panel as Class I, 21 CFR 880.6250, Patient Examination Glove, 80LYY, and meets all requirements of ASTM Standard D 3578-01a$^{\epsilon 2}$.

5. Intended Use:

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

6. **Comparison to Predicate Devices:**

   Shijiazhuang Tillotson Rubber Products Co., Ltd. Powder Free Natural Rubber Latex Patient Examination Gloves with a Protein Labeling Claim (50 micrograms or less) and Made from Allotex® an Enzyme Treated Natural Rubber Latex is substantially equivalent in safety and effectiveness to the Syntex Healthcare Products Co., Ltd. Powder Free Latex Examination Glove with Protein Labeling Claim (50 micrograms or less).

7. **Discussion of Non-Clinical tests Performed for Determination of Substantial Equivalence are as follows:**

   The standards used for Shijiazhuang Tillotson Rubber Products Co., Ltd. glove production are based on ASTM D 3578-01a$^{\epsilon 2}$. All testing meets requirements for Physical and Dimensions Testing conducted on gloves, Inspection Level S-2, AQL 4.0.

   The "Maximum Fill" Water Fill Test was also conducted with samplings of AQL 2.5, Inspection Level G-1, meeting these requirements. Primary Skin irritation and Skin Sensitization (allergic contact dermatitis) testing was conducted with results showing no primary skin irritant or sensitization reactions.

   There are no special labeling claims and we do not claim our gloves as hypoallergenic on our labels.

A Residual Powder Test that based on ASTM D6124-01 for Starch at finished inspection is conducted to insure that our gloves meet our "powder-free' claims (contain no more than 2 mg powder per glove).

8. **Discussion of Clinical Tests Performed:**

   Not Applicable – There is no hypoallergenic Claim.

9. **Conclusions:**

   Shijiazhuang Tillotson Rubber Products Co., Ltd. Powder Free Natural Rubber Latex Patient Examination Gloves with a Protein Labeling Claim (50 micrograms or less) and Made from Allotex® an Enzyme Treated Natural Rubber Latex conform fully to ASTM D 3578-01a$^{\epsilon 2}$ standard as well as applicable 21 CFR references, and, meets pinhole FDA requirements, biocompatibility requirements and labeling claims as shown by data in Section 7. There are no safety/efficacy issues or new claims from the "substantial equivalence" products cited.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 8 2005

Shijiazhuang Tillotson Rubber Products Company Limited
C/O Mr. James Chu
Official Correspondent
Gloveco, Incorporated
590 West Central Avenue, #D Suite
Brea, California 92821

Re: K043014
Trade/Device Name: Powder Free Natural Rubber Low Modulus Latex Patient Examination Gloves with a Protein Labeling Claim (50 Micrograms or Less) and made from Allotex an Enzyme Treated Natural Rubber Latex
Regulation Number: 880. 6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYY
Dated: December 21, 2004
Received: January 12, 2005

Dear Mr. Chu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043014

Device Name: Powder Free Natural Rubber Low Modulus Latex Patient Examination Gloves with a Protein Labeling Claim (50 micrograms or less) and Made from Allotex an Enzyme Treated Natural Rubber Latex

Indications For Use: A patient examination glove is disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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